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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/645,055

08/21/2003

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EXAMINER

CAMPBELL, VICTORIA P

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

11/10/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/645,055	Applicant(s) DEVENS ET AL.	
	Examiner VICTORIA P. CAMPBELL	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,8-26,39-44,46 and 47 is/are pending in the application.
- 4a) Of the above claim(s) 9,11,13,15,16,18-26 and 39-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8,10,12,14,17,42,43,46 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is the second Office Action following the Request for Continued Examination based on the 10/645055 application filed August 21, 2003. Claims 1-5, 8, 10, 12, 14, 17, 43, 44, 46, and 47 as amended are currently pending and considered below.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The examiner notes the portions defined in claim 14 (a cone portion and a body portion each extending along the entire length of the balloon) is not disclosed in the specification or the drawings originally filed by applicant.
3. Claims 46 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The examiner notes that mere absence of

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positive recitation in an applicant's specification is not enough to support the use of a negative limitation in the claims. MPEP 2173.05(i).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-5, 8, 10, 12, 14, 17, 43, and 44 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over USPN 6,364,856 B1 to Ding et al.

Regarding claims 1-3, 8, 10, 12, and 14, Ding et al disclose a medical device comprising a balloon (3) comprising a first portion having a first length (2), and a second portion disposed on the first portion having a second length (4), wherein the second portion defines an outer surface of the balloon; wherein the first portion varies in thickness along the first length and the second portion varies in thickness along the second length (Figs. 2a, 2b; see right hand side), wherein the balloon has a body

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portion and a cone portion and wherein the first portion has a great thickness at the body portion than at the cone portion (Fig. 2b; the body portion of the first portion is thicker than the tapered portion of the cone; see Fig. 2b reproduced below for clarification).

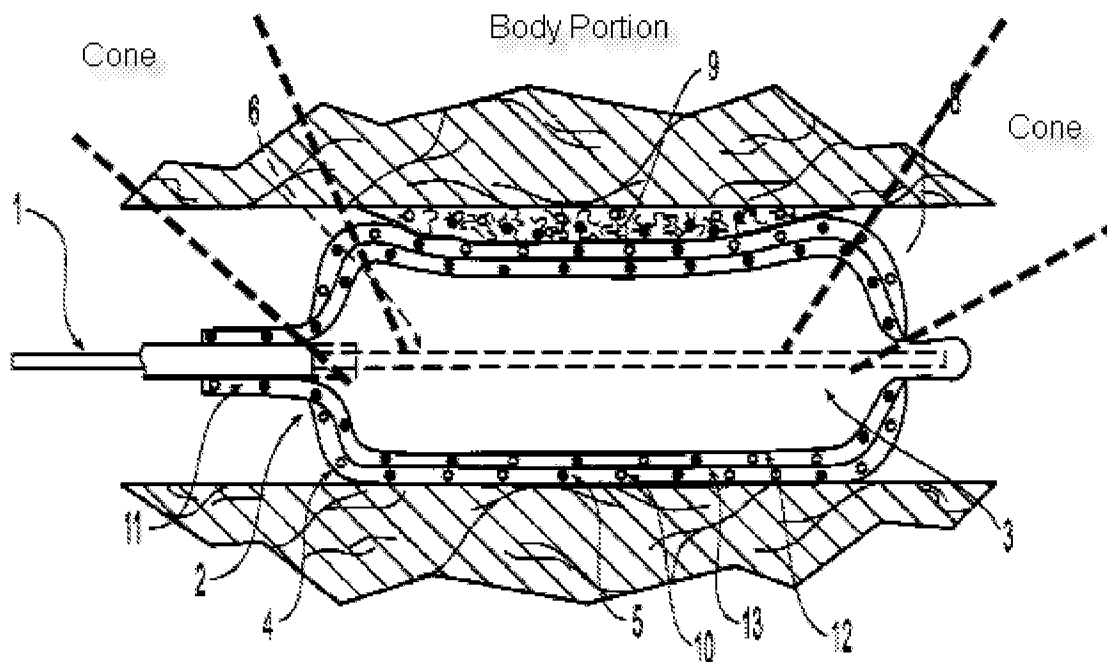


Fig. 2b

Ding et al further disclose that the first and second portions have different compositions (the first portion is a reservoir, the second is a sponge material), that the second portion is disposed substantially entirely on the first portion, that the thickness of the first and second portions is generally constant in the cone portion (the tapering of the portions takes place only at the most extreme end of the cone portions, and therefore the thickness is maintained along substantially the entire length), and that the portions extend substantially the entire length of the balloon (Figs. 2a and 2b).

Regarding claims 4, 5, and 17, Ding et al do not explicitly teach or disclose that the first and second portions have different hardness, that the second portion is softer

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than the first portion, or that the cone portion is more flexible than the body portion.

However, these properties of the first and second portions are either inherent or obvious to one having ordinary skill in the art at the time the invention was made, as material selection from those commonly used in the art is considered obvious. In addition, because the first and second portions taper sharply at the end of the cone portion, the examiner believes this would impart additional flexibility to the cone portion because, in general, when the thickness of a material is decreased, its flexibility is increased.

Regarding claims 43, Ding et al disclose a medical balloon (3) comprising a plurality of layers including a first layer formed from a first material (2) and a second layer formed from a second material different than the first material (4), wherein the first layer varies in thickness axially along the balloon (Figs. 2a and 2b), and includes a first thickness adjacent a waist portion of the balloon (see right terminus of the first layer at the right-hand side of Figs. 2a and 2b), and a second thickness greater than the first thickness adjacent a body portion of the balloon (Figs. 2a and 2b), and wherein the second layer varies in thickness axially along the balloon (Figs. 2a and 2b).

Regarding claim 44, Ding et al also disclose that the balloon includes a tapered portion (see “cone” in the labeled Fig. 2b reproduced above), but do not explicitly teach or disclose that the body and tapered portions have different stiffness. Because the first and second layers taper sharply at the end of the tapered portion, the examiner believes this would impart additional flexibility to the tapered portion because, in general, when the thickness of a material is decreased, its flexibility is increased, and therefore its stiffness is decreased.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al in view of USPGPub 2002/0122903 A1 to Ferrera et al.

Regarding claim 46, Ding et al teaches a medical balloon (3) comprising a plurality of layers including a first layer (2) formed of a first material and a second layer (4) formed of a second material different from the first material, wherein the first layer varies in thickness axially along the balloon and includes a first thickness adjacent a waist portion of the balloon and a second thickness greater than the first thickness adjacent a body portion of the balloon and wherein the second layer varies in thickness axially along the balloon (Figs. 2a, 2b; see right hand side).

Ding et al do not disclose that the first and second layer are free of sponge coating and/or a drug, but Ferrara et al disclose a balloon (20) having two layers (22 and 24) each of which is a polymer which is free of a drug. At the time of invention, it would have been obvious to make the balloon of Ferrara et al using the design of Ding et al in order to provide a smaller profile to the balloon for insertion and removal purposes.

Response to Arguments

11. Applicant's arguments filed July 23, 2009 have been fully considered but they are not persuasive.

12. Regarding applicant's argument that the second portion of Ding et al as described by the examiner is simply a coating and therefore does not define an outer surface of the balloon, the examiner disagrees and notes that by coating the sponge coating onto the existing balloon layer, the balloon becomes a multi-layer balloon with the coating (second portion) defining the outer surface of the balloon.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell
Examiner, AU 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763